

claim 32.

Claims 22 and 23 (canceled claims 31 and 32 in the parent application) are supported by original claim 5 and the disclosure at page 5, lines 15-18 of the specification, referring to stringent conditions as disclosed by the Southern et al. reference to wash hybridization strips (page 507 and 510 of Southern et al.). Moreover, Applicant incorporated the Southern et al. reference in its entirety in the present application at page 5, lines 9-11. Therefore, the claims are fully supported, no new matter has been added, and the claims are entitled to the priority date of the parent application.

Applicants have also amended the specification at page 5, line 18 to incorporate a specific section of the Southern et al. reference, referring to the hybridization conditions of "1xSSC at 65°C." This amendment is accompanied by a declaration pursuant to MPEP §608.01(p) and *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973), *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973) and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973). This amendment simply incorporates a portion of the Southern et al. reference that was previously incorporated in its entirety in the parent application. Therefore, this amendment does not constitute new matter, and the amendment is entitled to the priority date of the parent application.

Background

Prior to filing of this divisional application, The Examiner rejected claim 22 (canceled claim 31 in the parent application) in her April 20, 1998 Office Action in the parent application, as being indefinite and vague under 35 U.S.C. §112, second paragraph. In particular, the Examiner stated that the "particular assay conditions are not precisely defined in the specification." In that same Office Action, the Examiner also rejected claim 23 (canceled claim 32 in the parent application) under 35 U.S.C. §112, first paragraph, as containing new matter because the claimed conditions are not explicitly set forth in the passage, and the reference teaching manual (Maniatis) does not define a particular set of conditions which are defined as "stringent."

To further clarify the specification in response to the Examiner's rejections, Applicant amended the specification to include a specific portion of the Southern et al. reference in the Applicant's September 2, 1998 Amendment. The portion previously amended to the specification in the parent application is the same portion of Southern that has been amended to the specification in the present Preliminary Amendment. In the Examiner's September 24, 1998 Advisory Action, the Examiner maintained her previous rejections and refused to enter the amendment, stating that the amendment introduced new matter because Southern et al describes multiple hybridization conditions, none of which were specifically referenced or defined as "stringent" in the reference. Therefore the Examiner stated that "the generic incorporation by reference does not direct one to the particular passage which applicants are relying on for support" and therefore this

passage was new matter.

In support of the amendment of the specification to incorporate a portion of Southern, Applicant submitted an *In re Hawkins* declaration following the Applicant's Notice of Appeal filed October 28, 1998. However, in the Examiner's Office Action mailed November 3, 1999, the Examiner maintained the new matter rejection and stated that *In re Hawkins* was inapplicable to the present situation since *Hawkins* required specific incorporation of page and verse.

The Applicant disagrees with the Examiner's earlier rejections for the reasons previously made of record and for the following reasons.

Rejection of claim 22 for "stringent conditions"

Claim 22 recites an isolated and purified nucleic acid which is hybridizable to SEQ ID NO.1, under stringent conditions. Applicant emphasizes that what is claimed is the hybridizable nucleotide, as opposed to a process limited to specific stringent conditions. In addition, the stringent conditions referred to in claim 22 are fully supported by the specification and fully defined for the following reasons:

First, "stringent conditions" is a term well-known and frequently used in the art. Thus, a person of ordinary skill in 1993 would have no trouble understanding the term nor what is referred to in Southern. As set forth in the Applicant's previous response of January 27, 2000, a cursory search for the terms "stringent or stringency

w/3 condition(s) w/6 hybridization" in U.S. Patents filed before 1994 resulted in 833 patents.

Second, Applicants were entitled to incorporate into the specification the entire Southern reference. The Southern reference is only an article, 18 pages long, and discloses a number of conditions that are stringent. Applicants were entitled by law to incorporate the entire reference, but have not done so in the interest of brevity. If the Examiner wishes, the entire Southern reference can be inserted in the specification.

Third, the contents of the Southern reference are well-known in the art, and Applicants were not required to incorporate them by reference at all. Applicant's attorneys telephoned Scientific Citations and were told that the Southern article has been cited over 20,000 times in the technical and scientific literature. As set forth in the Applicant's response of January 27, 2000, a search of U.S. patents revealed that the Southern article is cited in the specification (not in the list of prior art) in 560 U.S. patents at least 150 of which were already issued in June 1993. Accordingly, the Southern reference can be considered a standard reference in the art and the hybridization conditions set forth in Southern are well-known such that a person skilled in the art would have no trouble understanding that "stringent hybridization conditions" would have meant conditions no less stringent than 1X SCC at 65°C as found in the Southern reference, or the equivalent (higher salt concentration at a lower temperature). Accordingly, those skilled in the art would readily understand what the phrase "stringent conditions" meant as used in the specification and how the phrase

was applied to the Southern article. Thus, the use of the Southern article to illustrate stringent conditions is unambiguous.

Fourth, the phrase "stringent conditions" was never meant to be a direct quotation. As the Applicant has previously noted, the phrase was placed in quotation marks to indicate that the phrase was being defined in the specification and that, when used in the specification, would have the defined meaning. The Examiner statement that the Applicant's use of the word "by" in the passage "Stringent conditions' are as defined by (emphasis added) Southern ..." implies a direct quotation is not supported by any rule of interpretation or case. Applicant's definition of "stringent conditions" to encompass the hybridization conditions disclosed in Southern is entirely consistent with the use of the word "by" in the quoted passage. Moreover, the defined term "stringent conditions" is one in a list of six defined terms set forth in quotation marks on pp. 5-6 of the specification. There is no reason why the person of ordinary skill would interpret "stringent conditions" to be a direct quotation but all the other terms to be simply defined terms.

Rejection of claim 23 for "1XSSC at 65°C" conditions

Even assuming that the Applicants improperly defined stringent conditions and that Southern does not disclose stringent conditions, then the Applicant's are still entitled to a claim specifying the conditions of "1XSSC at 65°C" as specified in Southern.

First, Applicants were entitled to incorporate into the specification the entire Southern reference. As the Applicant has previously stated, the Southern et al. reference was incorporated in its entirety by the specification on page 5, lines 9-11. Therefore the Applicant was entitled to incorporate the entire Southern reference, but did not do so in the interest of brevity. However, if the Examiner so wishes, the entire Southern reference can be inserted in the specification.

Second, Southern et al. discloses a number of hybridization conditions, including 2X SSC, 6X SSC, 4X SSC, and 1X SSC at the disclosed temperature(s) (See, e.g., Plate II in the Southern reference). Applicant clearly and properly incorporated Southern et al. in its entirety in the original specification. Because Southern et al. specifically discloses a range of conditions, including 1XSSC at 65°C, Applicant's claiming of that particular condition is fully supported in the original specification and does not constitute new matter.

Third, even assuming that Applicant's incorporation of the Southern reference was defective, such defect has been cured by Applicant's use of an *In re Hawkins* declaration pursuant to MPEP §608.01(p), ¶6.19. The Examiner's previous objection to the Applicant's *In re Hawkins* declaration is based on an apparent misreading of the *In re Hawkins* decisions.

According to the Examiner, *In re Hawkins* is distinguishable because *In re Hawkins* "specifically directed one skilled in the art to specific compounds and the methodology used to make them in the identified" references. The Examiner's interpretation of this passage as requiring a specific citation of page and paragraph is

incorrect. In the case of *In re Hawkins*, the court held as sufficiently specific a reference to application serial numbers: “These novel compounds may for example be used in the production of valuable monomers for example by the processes described in copending British applications 36107/66, 42756/66, 46971/66, 49699/66, 50324/66, 10070/67, and 10071/67.” *Hawkins*, 179 USPQ at 159. The *In re Hawkins* reference consisted of string cites that were no more specific in terms of pointing to a chapter and verse within each cited reference (and due to their large number could be considered to be even less specific) than Applicant’s reference to a single article in the present situation. Therefore the court in *In re Hawkins* held that a later amendment based on these string cites was “not new matter within the meaning of 35 U.S.C. §132 ...” because the information was “identified and specifically referred to for that information in the U.S. application as filed.” *Hawkins*, 179 USPQ at 162. Clearly, Applicant’s incorporation of the Southern article “in its entirety” meets and exceeds the level of specificity found *In re Hawkins*. Therefore Applicant’s *In re Hawkins* declaration is proper and incorporation of the Southern material into the specification is in compliance with MPEP §608.01(p), ¶6.19.

Likewise, notwithstanding the Examiner’s assertion otherwise, the case law, including *In re Voss*, 194 USPQ 267 (CCPA 1973) and *In re Fouche*, 169 USPQ 429 (CCPA 1971), support the Applicant’s position. The court *In re Voss* held that an earlier rejection, based on *In re Seversky* 474 F.2d 671, 177 USPQ 144 (CCPA 1973), confused two different concepts: “(1) the right to have the benefit of the filing date of an earlier application under [35 USC §] 120 ... and (2) the incorporation by reference in an

application of matter elsewhere written down (not necessarily in a patent application), for economy, amplification, or clarity of exposition ...” Voss, 194 USPQ at 270 (emphasis added). In the latter case of the situation where a reference incorporates material only for the purpose of economy, amplification or clarity, the court held that the incorporation of “Reference is made to United States Patent No. 2,920,971, granted to S.D. Stookey, for a general discussion of glass-ceramic materials and their production” was sufficiently specific without need for column and lines to allow later importation of material from the incorporated reference. Voss, 194 USPQ at 270.

Similarly, in *In re Fouche*, the court held that “identification was reasonably precise,” even though the “appellant could have used a more precise identification technique ... [and] the technique used does not absolutely distinguish the application sought to be referenced from all other possible applications.” *Fouche*, 169 USPQ at 431 (emphasis added). As in the above cases, Applicant referenced “stringent hybridization” conditions in Southern for the purposes of economy, amplification, or clarity of exposition. Therefore, like *In re Voss* and *In re Fouche*, and unlike a situation where reference is made in order to claim the benefit of an earlier filing date, Applicant in the present situation need not reference to a specific page or paragraph. As a result, *In re Voss* and *In re Fouche* are directly on point and Applicant’s reference to Southern in the present specification has at least the necessary specificity.

The Examiner also cites a portion of MPEP section 608.01(p), which states “Particular attention should be directed to the specific portions of the referenced

document where the subject matter to be incorporated can be found.” The Examiner states that since the entirety of the reference is cited, it is unclear which portion of the reference Applicant is relying upon. First, Applicant notes that “the Manual of Patent Examining Procedure is merely a guide to the Examiner and is not controlling where it conflicts with the statutes and Rules of Practice.” *Hawkins*, 179 USPQ at 160. A specific reference does not necessarily mean reference to a specific page number or portion. Second, Applicant has identified the referenced background material with sufficient specificity as required by the case law. The decisions in *In re Hawkins*, *In re Voss* and *In re Douche* clearly hold that reference to specific pages or paragraphs is not necessary where material is incorporated for economy, amplification or clarity, and in any event the referenced material here is only one article and is incorporated in its entirety in the specification at p. 5, lines 9-10. The Examiner cites to no case which requires reference to a specific page number or portion for referenced material of reasonable length, such as an article, already incorporated “in its entirety.” Third, reference to a specific portion of the Southern reference is not necessary because the Southern article is extremely well known in the relevant field of biology. As set forth earlier, the Southern reference is an old, well-regarded article that has been cited ample times. The hybridization conditions set forth in Southern are well-known in the field. A person skilled in the art would have no trouble understanding what conditions in Southern Applicant’s phrase “stringent conditions” referred to.

In view of the above remarks, Applicant respectfully submits the claims 2 and 23 are definite, enabled, supported by the specification, and do not constitute new matter. Applicant therefore submits that the claims are in condition for allowance, and a notice to that effect is respectfully requested.

Respectfully submitted,



Adda C. Gogoni, Esq.
Reg. No. 29,714
Attorney for Applicant(s)

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DARBY & DARBY P.C.
805 Third Avenue
New York, New York 10022
212-527-7700